| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/840,205 | BANAS ET AL. | |
| | Examiner | Art Unit | |
| | SUBA GANESAN | 3774 | |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20090701* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Arguments*

1. The amendment to claims 1, 13 and 18 is sufficient to overcome the rejection under 35 USC 112.

2. Applicant's arguments With respect to the combination of Palmaz and De Goicoechea (Claims 1-4, 13-15 and 17-20) have been considered but are not persuasive.

Applicant argues that Palmaz does not teach a graft with an undulating pattern, but rather only discusses an undulating pattern with respect to stents. This is not persuasive. Palmaz describes the fabrication of "structural members" by etching around masked regions of a tube of thin-film graft material (see pg. 6 lines 16-19, pg. 13 lines 1-7, pg. 14 lines 14-20, and pg. 18 lines 10-14). It is clear from these excerpts that he structural members are simply thicker portions of the deposited film. Thus the characterization of the undulating pattern of Palmaz as only referring to a stent is inaccurate. Furthermore, Examiner notes that the difference between the Palmaz "stent" and applicant's "graft" is nominal only; both are structurally the same, in that they are tubular prosthesis formed via thin film deposition.

Applicant argues that the undulations taught by Palmaz are formed in the walls of the body member, that is, they are coplanar with the tubular wall of the stent. This is not persuasive. While Palmaz does not clearly disclose circumferential corrugations along the length of the stent forming an undulating pattern of peaks and valleys in each of the luminal and abluminal surfaces, Palmaz does discuss removing material such that the

structural members are thicker than the interstitial webs (structural members 22 and interstitial webs 24, in the case of fig. 1 and 2). Such a structure results in circumferential corrugations 22 forming an undulating pattern of peaks and valleys in the abluminal surface (see fig. 2). Also see figure 7, in which the luminal and abluminal surfaces have been etched to form the thicker corrugations 52.

Applicant argues that one would not combine the crimped graft of Goicoechea with the thin film of Palmaz because the stent/graft of Palmaz is designed to expand whereas the crimped graft of Goicoechea is not. Examiner disagrees. There is no evidence that the graft of Goicoechea cannot be folded and deployed in an expanded state. Thus modification of Palmaz to include the corrugated structure of Goicoechea does not change the principle operation of the graft of either Palmaz or Goicoechea.

Lastly, applicant argues that one of ordinary skill in the art would not be enabled to make a combination of the material and fabrication of Palmaz with the specific pattern of Goicoechea. Examiner disagrees. Palmaz discloses several methods of fabricating the disclosed stent/graft, including deposition and etching. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine a thin film deposited graft with unitary structural support members as taught by Palmaz with a specific pattern of structural support (ie an undulating structure) as taught by Goicoechea, since doing so would be a substitution of the structural members of Palmaz with the undulating structure of Goicoechea, both designs arriving at the same purpose: providing a stronger graft.

3. With respect to the rejections of claims 5, 12 and 16, Van Schie et al teaches an implantable medical graft comprising at least one suture member integrally extending along the longitudinal axis and through suture holes (e.g. Figs 4 and 6).

4. With respect to claims 6-10, the non-undulating portions of Palmaz are located at either end of the stent. Kona provides reasoning for increasing the thickness of the ends of the stent. When combined with Palmaz, this yields thicker non-undulating portions. With respect to claim 7, the claim language "about" broadens the range to encompass a thickness of 10 micrometers. With respect to claims 9-10, a teaching for Y shaped connectors has been provided.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe microperforations present only in the valleys of the undulating pattern. Examiner suggests amending the claim to include the particulars of figure 13 as described in the specification to overcome this rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-4 and 13-15, 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) in view of De Goicoechea et al. (5383927).

6. Palmaz et al discloses an implantable medical graft, comprising: a. a generally tubular body member comprising a film selected from the group consisting of metallic and pseudometallic materials (page 17, lines 1-7); and b. at least a portion of the body member having a plurality of undulations formed in walls of the body member by a support arranged in any manner as is known in the art of stent fabrication (page 5, lines 16-20, also see fig. 2 and 10, noting structural members 22 are thicker than the interstitial webs 24), and microperforations (e.g. Figs. 2-3 and 8A-8C).

7. However, Palmaz et al does not disclose the support arranged ***specifically*** as having continuous circumferential undulations. De Goicoechea teaches a vascular graft structure with continuous circumferential undulations (see fig. 1A) resulting in a prosthetic graft with stronger walls. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the graft of Palmaz with continuous circumferential undulations as taught by De Goicoechea for the purpose of providing a stronger graft wall.

Palmaz discloses several methods of fabricating the disclosed stent/graft, including deposition and etching. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine a thin film deposited graft with unitary structural support members as taught by Palmaz with a specific pattern of structural support (ie an undulating structure) as taught by Goicoechea, since doing so would be a substitution of the structural members of Palmaz with the undulating structure of Goicoechea, both designs arriving at the same purpose: providing a stronger graft. Such a substitution of one known equivalent element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

With respect to claim 2, Palmaz discusses selectively placing patterns of openings (figs. 8A-C). One of ordinary skill in the art would understand that the pattern can be selectively placed to achieve varying sites for cellular migration. Such a modification of Palmaz would have occurred using known methods and yielding predictable results. With respect to claims 4 and 18, Palmaz teaches portions of the graft without support members (see fig. 3).

With respect to claim 17, Palmaz in view of Van Schie discloses the circumferential corrugations as claimed. The resultant combination would be fully capable of bending in excess of 180 degrees about the longitudinal axis, since Palmaz discloses thin film deposition, which results in a thin and flexible prosthesis.

8. Claims 5, 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al in view of De Goicoechea et al. (5383927), as applied above and further in view of Van Schie et al (6,974,471 B2).

9. Palmaz et al discloses an implantable medical graft as above. However, Palmaz et al does not disclose at least one suture member integrally extending along the longitudinal axis and through suture holes. Van Schie et al teaches an implantable medical graft comprising at least one suture member integrally extending along the longitudinal axis and through suture holes (e.g. Figs 4 and 6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of at least one suture member integrally extending along the longitudinal axis and through suture holes, as taught by Van Schie et al, to an implantable medical graft as per Palmaz et al, such that "the device can be curved in situ to fit the curved lumen" as found in Van Schie et al (col. 1, lines 44-52).

10. Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al in view of De Goicoechea et al. (5383927) and Van Schie et al (6,974,471 B2) as applied above, and in further view of Kula et al (6,325,825 B1).

11. Palmaz et al in combination with De Goicoechea and Van Schie teaches an implantable medical graft as above. However the combination lacks the thickness of the undulating regions as less than that of the non-undulating regions. Kula et al teaches an implantable medical graft having thicker ends, which correspond to the non-undulating regions of Palmaz et al/ Van Schie (col. 4, lines 60-66). It would have been obvious to

one having ordinary skill in the art at the time the invention was made to combine the teaching of an implantable medical graft having thicker ends, as taught by Kula et al, to an implantable medical graft as per Palmaz et al/ Van Schie, in order to "protect the artery and any plaque from abrasion that may be caused by the stent 10 ends during insertion of the stent 10. The modification also may provide increased radio-opacity at the ends of the stent 10. Hence it may be possible to more accurately locate the stent 10 once it is in place in the body" as found in Kula et al (col. 4, lines 60-66).

Regarding claim 7 Palmaz et al/ Van Schie in further view of Kula et al fail to disclose the **specific** thicknesses of the claimed regions. However, Palmaz et al discloses that the thickness of the microperforated material is approximately 10 micrometers (page 21, lines 13-14). Palmaz et al also discloses that the undulations may be formed by a "subtractive" method (Fig. 10). The reduction of the undulation region relative to the non-undulated region would result in a thickness of the thinner region ***about*** 3-7 micrometers.

12. With respect to claims 9 and 10, Palmaz et al/ Van Schie/Kula fail to disclose the suturing openings as cruciform or generally Y-shaped slots. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to make the slots these shapes. Applicant has not disclosed that these shapes provides an advantage, is used for a particular purpose, or solve a stated problem, and therefore appear to be a matter of obvious design choice. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the holes of Van Schie et al or the claimed slots because both allow for the

passage of sutures. Furthermore such shaped holes for sutures are known in the art (Moser U.S. Pat. No. 5725556). Therefore, it would have been obvious to one of ordinary skill in the art to modify the cited references to obtain the invention as specified in claims 9 and 10. Please note that the Applicant may have intended to claim the microperforations as cruciform or generally Y-shaped slots.

13. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al and De Goicoechea et al. (5383927), as applied above and further in view of Banas et al (5,749,880).

14. Palmaz et al discloses an implantable medical graft as above. However Palmaz et al does not disclose the implant having barbs. Banas et al teaches an implantable medical graft having projecting barb members (col. 14, lines 48-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of projecting barb members, as taught by Banas et al, to an implantable medical graft as per Palmaz et al, in order to aid in anchoring to the target blood vessel wall, as in Banas et al (col. 14, lines 48-54).

***Conclusion***

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./
Examiner, Art Unit 3774

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